UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,356	07/22/2002	Michele Trucksis	VET-1	9079

23599 7590 10/14/2003

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,356	TRUCKSIS, MICHELE	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31July2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,19,21,22,25,41-47,50 and 77-89* is/are pending in the application.

4a) Of the above claim(s) *1-5,41,42,46,50 and 77-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10,19,21,22,25,43-45,47 and 84-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,19,21,22,25,41-47,50 and 77-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's Response to Restriction Requirement, received 31July2003, paper$9, is acknowledged.

Applicant elects, with traverse, Invention III, claims 6-10, 19, 21, 22, 25, 43, 45, 47, and 84-89, drawn to avirulent *Mycobacterium tuberculosis*, a method of making, and a first method of use. The traversal is on the grounds that the examiner has not addressed the issue as to how examination of a broader scope of subject matter would impose undue searching burden. This is not found persuasive because while the searches of the individual inventions may overlap, the searches are not coextensive and they lack the same or corresponding special technical features as put forth in the original restriction requirement. The requirement is still deemed proper and is therefore made FINAL.

Applicant elects the gene Rv2348C in the Election of Species requirement.

Claims 1-10, 19, 21, 22, 25, 41-47, 50, and 77-89 are pending. Claims 1-5, 41, 42, 46, 50, and 77-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 6-10, 19, 21, 22, 25, 43, 44, 45, 47, and 84-89 are under consideration.

Drawings

3. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Figure 11 contains several sequences, but only two are identified by the required sequence identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6-8, 45, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because it depends from a nonelected claim. Claims 7, 8, and 45 each depend from claim 6, but do not correct the indefiniteness.

Claim 47 recites a method to elicit an immune response in a patient "in need of such treatment". However, there is no recitation defining the phrase "such treatment".

7. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis, because the claim recites the limitation "gene 008381" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 9 from which claim 19 depends does not recite "gene 008381".

8. Claims 43-45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim 43 is drawn to a "pharmaceutical" composition.

M.P.E.P. §2164.01(c), paragraph 3, recites:

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See in re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceutics"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease"

While the definition of "pharmaceutical" is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant application, the only examples of any injection into a recipient deals with *M. marinum*. The instant specification does not teach how to use the claimed composition, a pharmaceutical comprising *M. tuberculosis*, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered.

Claims 44, 45, and 47 are drawn to *M. tuberculosis* vaccines and a method to elicit an immune response in a patient in need of such treatment. The instant specification provides guidance/examples for only *M. marinum*. The production of *M. tuberculosis* vaccines and a method of using them appears to be merely speculation based upon the *M. marinum* examples.

9. Claims 6-10, 19, 21, 22, 25, 43-44, 47, and 84-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to *M. tuberculosis* virulence genes and avirulent *M. tuberculosis* bacterium. The instant specification provides only examples of virulence genes and avirulent *M. marinum*, and speculates that portions of the *M. tuberculosis* genome which appears to be "substantially identical" to *M. marinum* may be virulence genes in *M. tuberculosis* and if one mutagenized this region of *M. tuberculosis* one may obtain a possible avirulent *M. tuberculosis*. However, the specification does not actually provide examples that the *M. tuberculosis* genome which appears to be "substantially identical" to *M. marinum* genes are mutated or that if these regions are mutagenized one obtains an avirulent *M. tuberculosis*. Thus, the specification as a whole does not reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed avirulent *M. tuberculosis* or mutated genes of *M. tuberculosis*.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

October 13, 2003